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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/826,165
Filing Date: April 16, 2004
Appellant(s): KANIE, JIRO

Stephen P. Burr
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/16/09 appealing from the Office action mailed 7/16/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5.232.733 RESMER 8-1993

Kabushiki et al., "Total Parenteral Nutritional and Enteral Nutrition" Nippon Rinsho, Supl.5, vol59, no. 782 (May 31, 2001), pp. 283-307

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 10, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Resmer (USPN 5,232,733 hereafter '733). The claims are drawn to a semi-solid enteral nutrient product comprising a nutrient liquid and a semi-solidifying agent such as agar.

The '733 patent teaches a semi-solid eternal formulation comprising a nutrient liquid and an emulsifying agent (abstract). The nutrient liquid includes milk products such as skimmed milk and milk proteins along with semi-solidifying agents such as agar-agar (col. 2, lin. 38-45, examples 1-4). The product is semi solid with a viscosity of 70 cp and is used in feeding tube devices where this is delivered to the patient under pressure from an exterior device (col. 4, lin 49-60). The product is formed by mixing the nutrient liquid with the agar-agar components along with other nutritional components at an elevated temperature. The formulation is mixed, homogenized, cooled and stored (col. 3, lin. 65-col. 4, lin. 48).

Regarding the claim limitation drawn to the specific application site or operating procedures of the feeding tube and where the tube is placed are merely limitations reciting a future intended use for the enteral product. The enteral product of the '733 patent is structurally identical tot hat of the instant claims. It comprises a nutrient liquid and a semi-solidifying component such as agar. Applicant is reminded that where a patentee defines a structurally

complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Regarding claim limitations regarding the solidity of the product in the body, it is the position of the Examiner that such limitations would be inherently met by the '733 patent. The patent meets each of the compositional limitations of the claims namely it discloses an enteral feeding tube composition comprising a nutrient liquid and a semi-solidifying agents. By meeting these limitations any composition would inherently meet the functional limitation since those limitations would fall naturally from the properties of the components. Since a component and its properties cannot be separated the combination of the nutrient liquid and the agar must also remain in a semi-solid state in the intestine and not be affected by body temperature.

For these reasons the claims are anticipated by the '733 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Resmer et al (USPN 5,232,733 hereafter '733) in view of in view of Kabushiki et al (***Total Parenteral Nutritional and Enteral Nutrition***, pg 283-307, Suppl. 5, *Nippon Rinsho*, vol. 59, no. 782). The claims are drawn to a formulation for enteral administration comprising a nutritional liquid and a solidifying agent; wherein the mixture is fed through a feeding tube of predetermined internal diameter.

As discussed above the '733 patent discloses a formulation useful in enteral feeding tube devices comprising a nutrient liquid and agar as a semi-solidifying agent. The patent is however silent to the diameter of the feeding tube, though feeding tube diameters are commonly known in the art as seen in the Kabushiki reference.

The Kabushiki reference discloses an enteral feeding method. The device administers thick fluid diets such as puddings or crèmes, using feeding tubes with internal diameters larger than 4 mm (diagram). The routes of administration for the thickened feeding formulation can include oral for gastric catheterization, and one for direct trans-intestinal for feeding to the stomach (Figures). The tubing of the Kabushiki patent would provide an even flow to the thick composition avoiding air-bubbles that would adversely affect the patient.

Regarding the specific concentration of agar in the mixture is can be seen that the agar is added in an amount approximately 1.5 g/l to 343 g of diluting water. The formulation further comprises 6.0 grams of guar flour another semi-solidifying agent. In total there are approximately 7.5 grams of semi-solidifying agents to 343.00 grams of water. The claims recite

a 1 gram of agar per 200 ml of diluting water, measuring approximately 5 g/l of total formulation. By this ratio the prior at comprises approximately 4.37 g per 200 grams of water and well within the limits of the instant claims. It is the position of the Examiner that such concentration would have been obvious and are merely the result of an optimization of known ranges. The general conditions of the instant claims have been met, namely a small amount of agar added to a larger portion of water. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to combine the feeding tube formulation of the '733 patent into the enteral administration device of the Kabushiki reference in order to provide an enteral formulation high in calcium to a patient in need thereof. It would have been obvious to use a feeding tube of sufficient diameter in order to ensure even flow and distribution. One of ordinary skill in the art would have been motivated to combine theses disclosures with an expected result of an enteral feeding composition with a smooth even rate of flow directly to the intestine.

(10) Response to Argument

Applicant argues that:

A). **The Resmer patent does not disclose or suggest the instant claims, specifically each and every limitation of claims 8, 10, 11 and 13.**

Regarding argument A. it remains the position of the Examiner that the Resmer patent continues to anticipate the instant claims, specifically claims 8, 10, 11 and 13. The claims are drawn to an enteral formulation comprising a nutrient liquid and a semi-solidifying agent such as agar. The Resmer patent discloses an enteral formulation comprising at least agar and milk products. The instant claims recite that the formulation is semi-solid, and defines the semi-solid material and comprising only a mixture of a liquid nutrient solution and a semi-solidifying agent comprising agar that is added to the nutrient solution. The Resmer patent meets these compositional limitations. The Examiner has argued previously the functional limitations, though permitted and not improper, were in fact an inherent feature falling directly from the compositional limitations. Applicant asserts that the Office misunderstands the use of agar in the prior art. Applicant asserts that the Office assumes that the mere presence of agar in a specific concentration will render the limitations of the instant claims. However it is the instant claims that establish this fact. The instant claims recite that the semi-solidifying agent and liquid nutrient solution are present in a predetermined ratio sufficient to ensure a self supporting consistency. In other words, the mere presence of the semi-solidifying agent in relation to the nutrient liquid will establish the alleged novel and non-obvious physical characteristics. Applicant repeatedly asserts that the invention is not taught or suggested by the prior art, however it is the claims which are under Appeal and not the invention as a whole. Limitations of specification cannot be read into the limitations of the claims and as such only the claims can be

reviewed for patentability. The Resmer formulation meets the limitations of the claims, and as such anticipates the claims. The Resmer patent comprises a thickening, semi-solidifying composition comprising agar and a nutrient liquid consistent with the instant claims. For these reason the claims remain anticipated.

1. The Resmer formulation is not thick enough to overcome the drawbacks of the art or exhibit the characteristics of the instant invention.

Applicant makes this assertion by pointing out the viscosity of the Resmer formulation at room temperature. However the present claims are silent to the viscosity of the instant formulation. Applicant relies on the functional limitations that are dependent on the compositional limitations. The Resmer patent teaches an identical composition with a ratio providing a thickened enteral formulation. Applicant asserts that the formulation is merely an emulsion with solution properties; however emulsions differ in thickness and consistency depending on the other components present in the formulation. The formulation of the instant claims only requires agar and a nutrient liquid. The Resmer patent provides a formulation comprising agar and a nutrient liquid.

2. The Resmer patent does not disclose an enteral nutrition product for direct administration to the stomach.

As discussed above it is the position of the Examiner that such limitation are merely a future intended use and carry no patentable weight in view of the prior art. The prior art provides a structural identical formulation comprising agar and a nutrient liquid and as such anticipates the instant claims. Applicant is reminded that where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended

use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). As such the future intended use of the instant claims carries no patentable weight since the structure of the formulation defined in the compositional limitations is met by the prior art. Even if the limitation carried patentable weight the formulation of the Resmer patent is useful as a tube food, and is subject to external pressure during application.

3. The Resmer patent fails to disclose an enteral nutrition formulation for direct administration having a semi-solid consistency that is substantially self supporting that deforms without liquefying.

The Resmer patent discloses an enteral nutrient formulation comprising agar and a nutrient liquid. The semi-solid, substantially self supporting limitations are dependent on the ratio of semi-solidifying agent to the nutrient fluid; the instant claims are silent to the specific ratio. As such any ratio that results in a substantially self supporting formulation would meet the limitations of the claims. Substantially self supporting would indicate that the formulation is not as wholly self supporting such as a thick milk shake or a thin peanut butter. The Resmer formulation has a viscosity of 70 cp which is approximately as viscous as olive oil. A drop of olive oil will retain its shape upon pouring yet is not completely self sufficient such as a dollop of whipped crème or mayonnaise. The term *substantially* given its plane and broadest reasonable meaning in the instant claims would indicate that the formulation comprising agar and a nutrient liquid is more viscous than water but not quite as self supporting as peanut butter. As such the Resmer patent provides an identical formulation meeting he compositional limitations and thereby meeting the dependent substantial functional limitations.

4. The Resmer patent fails to disclose an enteral nutrition formulation for direct administration having a self supporting consistency that remains unchanged before during and after administration to the stomach.

Again Applicant asserts that the Resmer patent does not meet a functional limitation dependent on the compositional limitations of the instant claims. Applicant asserts without any support or comparative dated that the viscous fluid of the Resmer patent would somehow liquefy in the body. Applicant provides no evidence or support for this assertion, only that the stable viscous fluid has a viscosity of 70 cp at room temperature. Applicant implies that this would decrease at an elevated temperature; however one of ordinary skill in the art would recognize that all compound viscosities are reported at room temperature, regardless of the affect of temperature. The limitations regarding how the formulation is applied and to which body parts are again limitations drawn to future intended uses for the formulation and carry no patentable weight in view of the structurally identical and complete Resmer formulation. Further these limitations are more drawn to the administration technique and not the formulation itself. The method of administration has no bearing on the patentability of the formulation.

5. The Resmer patent fails to disclose an enteral nutrition product for enteral administration that is formulated to prevent gastro-esophageal reflux.

As stated above Applicant asserts that the Resmer patent does not disclose limitations either a. carry no patentable weight or b. depend from compositional limitations. As stated above the functional limitations of the instant claims are met by the compositional identical formulation of the Resmer patent. The future intended use limitations are not patentably distinct over the structurally identical Resmer formulation. Regarding specifically

gastro-esophageal reflux, Applicant asserts that the formulation is specifically formulated to prevent or treat such conditions in patients in need thereof. However the formulation only comprises a semi-solidifying composition and a nutrient liquid, which are taught in the Resmer patent.

B) **The combination of the Resmer and Kabushiki reference does not obviate the instant invention since each and every limitation is not taught of disclosed by the combination.**

1. The combination of the Resmer and Kabushiki does not obviate the instant invention since the Kabushiki reference does not overcome the deficiencies of the Resmer patent.

It remains the position of the Examiner that the combination of the Resmer patent and Kabushiki patent continue to obviate the instant claims. As discussed above the Resmer patent discloses an enteral nutrient formulation comprising a semi-solidifying composition and a nutrient composition. The Kabushiki reference is relied upon to establish the level of skill in the art regarding diameter of feeding tubes used in the art. Kabushiki is merely relied upon to establish that for thick nutrient formulation that can be delivered either orally or trans-intestinally the diameter of the larger than 4 mm. The Resmer patent discloses an enteral formulation comprising a semi-solidifying composition and a nutrient liquid that is delivered via an external pressure to the end user. The Kabushiki patent discloses a device specifically for thick nutrient formulations that can be delivered in a variety of manners, from traditional oral feeding tubes, to trans-intestinal direct tubes (Figures). It would been obvious to combine the formulation of the Resmer patent with the device of the Kabushiki reference since the Kabushiki reference is

designed for thick enteral formulations and would have provided a wide enough tube in order to provide smooth delivery. For these reasons the claims remain obviated.

2. *The PTO must consider secondary considerations associated with the present invention.*

As stated in the *Response to Amendment* section of the Office Action dated 7/16/08 the Declaration has been considered. However the Declaration was not sufficient to overcome the rejections based on 102(b) and 103(a). The Declaration establishes a long felt need for a viscous enteral nutrient formulation. The Examiner has never disputed any long felt need for such a formulation; however it remains the position of the Examiner that the formulation recited in the Declaration as a formulation meeting said long felt need is not commensurate in scope with the instant claims. The Declaration refers to a formulation comprising a specific concentration of agar to nutrient liquid and diluted water. This specific ratio is not represented in the claims and is not commensurate in scope. The ratio f the formulation of Appendix D has the nutrient liquid in equal proportion to that of diluting water. The formulation of the instant claims is complete silent to the concentration of the nutrient liquid in relation to the agar. Further the nature of the nutrient liquid is not clearly defined in the Appendix. Given the broadest reasonable interpretation the nutrient liquid is merely a solution that has *some* nutritional value. The milk products of the Resmer patent me this broad and reasonable interrelation. Regarding the alleged unexpected result, neither the Specification nor the Declaration provides a comparison showing the unexpected or superior nature of the ratios presented in the specification or recited in the claim. No direct comparison has been made with the closest prior art or any other formulations. It is the position of the Examiner that no

unexpected results have been reported, and as such the case for *prima facia* obviousness that has been established has not been overcome. Regarding the granting of Japanese license rights and profitability, the Examiner is in no position to comment on the validity, novelty or non-obviousness of protections granted outside of the United States. In accordance with current United States practice the instant claims have not been shown to be novel or nonobviousness over the prior art and remain rejected.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

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/Michael G. Hartley/

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